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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,807	07/29/2002	James Duncan Morrison	9013-46	2452

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EXAMINER
AUDET, MAURY A

ART UNIT	PAPER NUMBER
3654	9

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,807	MORRISON ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

35 U.S.C. § 371: Unity of Invention Requirement

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

The special technical feature linking the respective inventions to various compounds (Formula's I-III), compositions, processes of making, and processes of using, is the claim 1 preamble compound: an *amide of a bile acid/salt, with a substitutable amide bond loci* (for substitutions of various functional groups). Ruff et al. (Patent No. 5,446,026. Issued August 29, 1995; cited/applied in PCT-210, 408 of Applicant's PCT/GB00/02903), in claims 1-7, teaches an amide of a bile salt selected from cholate, deoxycholate and chenodeoxycholate wherein a group is bound to the bile salt at the amide bond loci (group bound is a calcitonin decapeptide amide). Therefore, the special technical feature that links the inventions does not "define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art".

Requirement for Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, Claims 1, 3-14, and 15-18, drawn to a compound of an amide bile acid/salt bound to a peptide, etc. of Formula I, and a composition containing the compound, classified in class 530, subclass 300+ (peptides of 3 to 100 amino acid residues), 345 (chemical aftertreatment); class 514, subclass 2+ (composition containing peptide); class 552, subclass 548-551 (various bile acids/salts).

II. Group II, Claim 2, drawn to a compound of Formula II, classified in class 530, subclass 300+, 345; class 552, subclass 548-551; class 436, subclass 142 (R6-alkylene substitution).

III. Group III, Claim 19, drawn to a process of making a composition comprising a compound (Invention I), classified in class 514, subclass 2; class 552, subclass 548-551.

IV. Group IV, Claim 20, drawn to a process of use of a composition comprising a compound (Invention I), classified in class 514, subclass 2+; class 552, subclass 548-551.

V. Group V, Claims 21-23, drawn to a compound (Formula III), classified in class 552, subclass 548-551; class 436, subclass 142; class 514+ (depending on which of the 40 pharmaceutically active agents claimed is attached).

VI. Group VI, Claims 21-23, drawn to a process of making a compound (Formula III) or composition of the compound, classified in class 552, subclass 548-551; class 436, subclass 142; class 514+ (depending on which of the 40 pharmaceutically active agents claimed is attached).

The compounds of Inventions I, II, and V are drawn to compounds and/or compositions that are related amide of a bile acid/salt, with a substitutable amide bond loci. However, because each Invention is of different chemical and/or peptide and/or pharmaceutical substitutions, each Invention differs in structure (chemically, physically, or pharmacologically) and in function. Therefore, a separate and distinct search is required for each Invention and each Invention is patentably distinct one from the other.

Inventions I and III are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products; (2) the product as claimed can be made by another and materially different process. (MPEP section 806.05(f)). In the instant case, the product (and hence composition) could be made by attaching the peptide of Formula I to a different position on the bile acid/salt, through a series of different chemical steps. Therefore, these Inventions are patentably distinct.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process, such as in antibody production, for example. Therefore, these Inventions are patentably distinct.

Inventions V and VI are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products; (2) the product as claimed can be made by another and materially different process. (MPEP section 806.05(f)). In the instant case, the product (and hence composition) could be made by attaching the pharmaceutically active agent of Formula III to a different position on the bile acid/salt, through a series of different chemical steps The processes of making or using in Inventions III, IV, and VI differ in the product used and/or the steps and results of the respective methods. Therefore, these Inventions are patentably distinct.

Requirement for Species Restriction

Additionally, a species election is necessary should Invention I or Invention V or VI be elected for examination on the merits.

I. As to Invention I, a species would need to be elected from the following two subsets directed to the amide of a bile acid/salt containing a peptide of Formula I:

A. Underivatised bile salt: one of the fourteen different salt species in claims 9-11; and

B. Peptide: one of the forty-seven different peptide species of claim 12, or

II. As to Invention V or VI, it is assumed that claim 23 is actually depending from claim 21, as opposed to claim 1 (where there is no antecedent basis). Therefore, a species would need to be elected from the 40 different pharmaceutical agents, directed to the compound/composition of Formula III.

Should Invention I, V, or VI constitute the elected invention, the invention will examined on the merits based on the respective elected species, directed to that Invention.

Should applicant traverse on the ground that the species in claim 2 or 14 and 20 are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the sequences unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other sequences or respective inventions.

Summary: Requirement for Restriction

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Request for Preliminary Set of Amended Claims

Based on the claims as originally filed, there are many dependencies, among the different inventions identified above. Additionally, many claims (i.e. claim 21) contain more than one statutory classes of inventions (i.e. claim 21, and depending claims 22-23, are directed to two invention classes: a compound and composition, a process of making). Also, claim 23 is improperly depending from claim 1, as there is no antecedent basis for a "pharmaceutical agent" (as noted above, claim 23 is assumed to depend from claim 21). As part of the election, Applicant is requested to submit a preliminary set of amended claims, directed to the elected invention, which do not contain any dependencies to any other non-elected inventions (claims), do not contain more than one statutory class of invention per elected set of claims, and which are fully descriptive of and include all limitations to that set of claims representing the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
January 27, 2003

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600